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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,372	07/27/2001	Preeti G. Lal	PC-0050 US	1477
27904	7590	04/20/2004	EXAMINER	
INCYTE CORPORATION 3160 PORTER DRIVE PALO ALTO, CA 94304			O HARA, EILEEN B	
			ART UNIT	PAPER NUMBER

1646

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/917,372	Applicant(s) LAL ET AL.	
	Examiner Eileen O'Hara	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 8-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-22 are pending in the instant application. Claims 2, 3 and 5 have been amended as requested by Applicant in the Paper filed September 22, 2003.

Claims 8-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Claims 1-7 are currently under examination.

Title

2. Applicants' amendment to change the title is acknowledged.

Withdrawn Objections and Rejections

3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 2 and 4-7 remained rejected, and claim 3 is now rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

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the application was filed, had possession of the claimed invention, for reasons of record in the previous Office Action, Paper No. 9, at pages 4-6, and below.

Claim 3 is now rejected because it encompasses an isolated cDNA comprising a nucleic acid encoding a protein of claim 1.

Applicants traverse the rejection on pages 6-13 of the response and assert that claim 2 has been amended to delete fragment language, and claim 1 recites only one specific fragment encoded by a polynucleotide of the invention, and thus the claimed fragments of the polynucleotides of the invention are adequately described. The Examiner agrees that these are adequately described. With regard to the “variants” or “homologues” of the polynucleotide of SEQ ID NO: 2 and the polypeptide of SEQ ID NO: 1, Applicants assert that they are described in sufficient terms that one of skill in the art would recognize Applicants’ possession of them in accordance with the written description requirements of 35 U.S.C. 112, first paragraph. On pages 7-8 of the response Applicants cite *Vas-Cath, Inc. v. Mahurkar*, and cite the Patent and Trademark Offices’ own guidelines in support of their position, and point to places in the specification where the sequences and variants are described. Applicants on pages 8-9 argue that the position of the Office Action is a misapplication of the law, and that the present claims specifically define the claimed genus through the recitation of chemical structure, and cite *Fiers v. Revel* and *University of California v. Eli Lilly and Co.*, as support that the recitation of structural features or physical properties are important factors to consider in a written description analysis, and that in a number of instances in which claims to DNA have been found invalid, the courts have noted that the claims attempted to define the claimed DNA in terms of functional characteristics without any reference to structural features. Applicants submit that in contrast to

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this, the variant language of independent claim recites chemical structure to define the claimed genus, and does not rely on functional characteristics.

Applicants' arguments have been fully considered but are not deemed persuasive. Under the Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, first paragraph, "Written Description", a representative species may be adequately described through its structure, through its functional characteristics, or through a combination of its structure and function. In the instant case the claims encompass polynucleotides having at least 85% identity to SEQ ID NO: 2 or polynucleotides encoding polypeptides at least 95% identical to the protein of SEQ ID NO: 1, and the specification discloses a single polypeptide and encoding polynucleotide, which is not adequately representative of a genus. Inclusion of a functional limitation to the claims would provide adequate written description and obviate the rejection.

Applicants also assert on pages 10-11 of the response that the claims at issue do not describe a genus which could be characterized as "highly variant" or which "vary substantially in length or composition", and submit Brenner et al., which discusses that low homologies over limited numbers of amino acid residues can identify proteins that are evolutionarily related or in signifying homology between proteins. Applicants submit that the claimed variation is far less than that of all potential TNF R2 related proteins related to SEQ ID NO: 1. Applicants' arguments on page 11 that Brenner's basic rule that sequence homology in excess of 40% over 70 or more amino acid residues yields high probability of functional homology have been fully considered but are not deemed persuasive. While such homologies can place proteins in evolutionarily related protein families, or in a specific protein family such as the TNFR family, the probability of predicting function from such low homology is low. Homology can place

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proteins in the same general family, such as cysteine-rich domains common to TNFR proteins, but the receptors in this family bind to different ligands, are expressed on different cell types, and have widely varying activities, as demonstrated by the Wallach review cited in the previous Office Action, and it is not predictable what the activity of a receptor is based on homology alone.

For these reasons, the rejection is maintained.

It is believed that all pertinent arguments have been answered.

Conclusion

5. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (571) 272-0871.

Official papers Before Final and After Final filed by RightFax should be directed to (703) 872-9306.

The customer service RightFax number is (703) 872-9305.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Eileen B. O'Hara, Ph.D.

Patent Examiner


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600